APR 0 1 2013

K130286

510(k) Summary Pursuant to 21 CFR 807.92

Sponsor: Pioneer Surgical Technology, Inc.
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Prepared: March 13, 2013

PIONEER SURGICAL

Trade name: Streamline MIS Spinal Fixation System

Common name: Pedicle Screw System

Classification: 888.3070 Pedicle Screw Spinal System; Class III

Product Codes/ Panel: NKB, MNH, MNI
Panel Code 87

Predicates:
K111502 Streamline TL Spinal System (SE 8-23-2011)
K101790 Quantum Spinal System (SE 3-7-2011)
K093771 Streamline MIS Cannulated Screw System (SE 8-10-2010)
K022949 Synthes USS (SE 3-24-2003)

Description:

The Streamline MIS Spinal Fixation System is a multiple component pedicle screw system comprised of a variety of components that allow the surgeon to build a spinal implant construct through an open or percutaneous approach. The implant components include rods, polyaxial pedicle screws with extended tabs, crosslinks, and locking set screws. The components are available in various sizes to accommodate differing patient anatomy. The system is attached to the pedicles by means of screws to the posterior, noncervical spine. The spinal construct is completed by connecting the screws with titanium alloy rods. Crosslinks can be used if additional stabilization is necessary.

All implant components of the Streamline MIS Spinal Fixation System are manufactured from the implant grade Ti 6Al/4V ELI Alloy, Grade 23 (ASTM F136).

The Streamline MIS Spinal Fixation System components are used with the Streamline TL System locking set screws and crosslinks, and the Quantum Spinal System Crosslinks.

The Streamline MIS Spinal Fixation System includes instrumentation to provide the surgeon with a minimally invasive approach for

posterior spinal surgery. Class I manual instruments are also included.

Intended Use:	The Streamline MIS Spinal Fixation System is intended for posterior, noncervical pedicle fixation, T1-S2. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion. The device is indicated for all of the following indications: degenerative disc disease (DDD) (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Streamline MIS instrumentation, when used with the Streamline MIS Spinal Fixation System, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.
Substantial Equivalence	This submission supports the position that the subject system is substantially equivalent to previously cleared pedicle screw systems based on comparison of indications for use, intended use, materials, technological characteristics, and pre-clinical performance testing.
Technological Characteristics:	The subject and predicate systems are overall similar in: - Intended use (described above) - Basic design: rod-based having screw anchors - Materials: Titanium Alloy per ASTM F136 - Sizes: dimensions comparable to predicates - Performance: ASTM F1717 equivalent results The fundamental scientific technology of the subject system is the same as predicate devices. There are no significant differences between the Streamline MIS Spinal Fixation System and the predicate devices which would adversely affect the use of the product.
Pre-Clinical Performance Data:	The subject system was evaluated per ASTM F1717 Static Compression Bending and Torsion, and Dynamic Compression Bending Testing and compared to predicate devices. This testing demonstrated that the device is as safe, as effective and performs as well as or better than the predicate device.
Conclusion:	The subject system is substantially equivalent to valid predicate devices and in this submission was found to be at least as safe and effective as the predicate device based on similarities in materials, technology, labeling and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Pioneer Surgical Technology, Incorporated
% Ms. Emily Downs
375 River Park Circle
Marquette, Michigan 49855

Letter dated: April 1, 2013

Re: K130286
Trade/Device Name: Streamline MIS Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Codes: NKB, MNI, MNH
Dated: February 1, 2013
Received: February 5, 2013

Dear Ms. Downs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

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510(k) Number (if known): K130286

Device Name: Streamline MIS Spinal Fixation System

Indications:
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The Streamline MIS instrumentation, when used with the Streamline MIS Spinal Fixation System, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130286